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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,877	02/24/2004	Mitsuo Fukuda	9694D-000002/US	8672

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HARNESS, DICKEY & PIERCE, P.L.C.
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RESTON, VA 20195

EXAMINER

KOTINI, PAVITRA

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/784,877

Applicant(s)

FUKUDA ET AL.

Examiner

Pavitra Kotini

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-10, 16, 18-22 and 24-26 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 11-15, 17 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/22/06, 5/16/05, 2/24/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 2 recites that the descending region area monotonically increases and the ascending region area monotonically decrease away from the point. This is opposite of what is set forth in claim 1 and in the specification

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bays et al. (US-4924865).

Bays discloses in one embodiment a first ascending region (18), a descending region (17), and a second ascending region (18) subsequently and integrally formed of biodegradable material (col.3, lines 8-10), extending from a point in a predetermined direction; wherein said first and second ascending regions have the largest cross

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section having substantially the same size and shape to each other (ascending region 18 is substantially the same along the entire structure).

Bays does not disclose the above embodiment to have a triangular cross section. However, the embodiment of figure 6 shows each of said regions having triangular cross sections taken along any planes perpendicular to the predetermined direction; said first and second ascending regions having the triangular cross sections of which area monotonically increases as being away from the point (fig. 7); and said descending region having the triangular cross sections of which area monotonically decreases as being away from the point (section 17 decrease in area away from the point and creates a waist). Therefore, it would have been obvious to a person of ordinary skill in the art to modify the frusto-conical shape of the first embodiment to have a triangular shape as taught in the embodiment of figures 6 and 7 (col.6, lines 51-63).

Regarding **claim 10 and 26**, a holding region (15) of biodegradable material (col.5, line 37) connected to said second ascending region (fig. 3).

Regarding **claim 16**, at least one groove (13) extending in the predetermined direction through at least one of said first and second ascending regions and descending region (fig. 3).

Claim 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bays et al. (US-4924865)

Bays discloses a first ascending region (18), a descending region (17), and a second ascending region (18) subsequently and integrally formed of biodegradable material (col.3, lines 8-10), extending from a point in a predetermined direction; wherein

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said first and second ascending regions have the largest cross section having substantially the same size and shape to each other (ascending region 18 is substantially the same along the entire structure), said first and second ascending regions having the cross sectional area of which monotonically increases as being away from the point (fig. 7); and said descending region having cross sectional area of which monotonically decreases as being away from the point (section 17 decrease in area away from the point and creates a waist).

Bays does not disclose a trapezoidal cross section taken along any plane perpendicular to the predetermined direction. The instant disclosure describes this parameter as merely providing a sharp penetration point and does not describe it as contributing any unexpected result, providing any advantage over other designs, or solves a stated problem to a tissue penetrating device.

At the time the invention was made, one of ordinary skill in the art would have expected Applicant's invention to perform equally well with a triangular or pyramidal cross-section because regardless of the shape, the penetration of a triangular or trapezoidal shaped lancet would achieve the same function or effect of repeatedly incising the peripheral cells and wedging away the intact tissue by the ascending regions and releasing the frictional forces with the peripheral cells by the descending regions. Also, as the specification states, both shapes would minimize pain to the patient by returning the peripheral cells to their original position. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of

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the ordinary artisan, obtained through routine experimentation in determining optimum results.

Claims 3-5, 8, 9, 20-22, 24, 25, rejected under 35 U.S.C. 103(a) as being unpatentable over Bays et al. Bays discloses the claimed invention except for values of the cross-section areas and the increasing rates (or slopes). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include precise values of the slope rates of the ascending and descending areas and the cross-sectional areas of these sections. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Allowable Subject Matter

Claims 6, 7, 11-15, 17 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PK
AU 3731
2/12/07


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

2/19/07